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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,837	03/24/2004	Wenfeng Xu	03-02	4419

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EXAMINER	
STOICA, ELLY GERALD	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/807,837	XU ET AL.	
	Examiner	Art Unit	
	Elly-Gerald Stoica	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) *1-7 and 23-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-22 and 55-60* is/are rejected.

7)☒ Claim(s) *8-10,12,13,56 and 57* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04/11/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Election/Restriction

1. Applicant's election without traverse of Group II, claims 8-22 and 55-60, drawn to an antibody that binds to a polypeptide, classified in class 530, subclass 388.22, in the reply filed on July 24, 2006, is acknowledged. The antibody is to be obtained by inoculating an animal with the polypeptide consisting of the amino acid sequence of SEQ. ID NO: 3 from amino acid number 1 (Pro), to the amino acid number 6 (Asp). The Applicant is advised to submit an amended set of claims that accurately reflect the elected claims.

Priority

2. Applicant's claim for the benefit of the provisional applications 60/457,481 03/24/2003 and 60/523,295 is acknowledged and therefore the priority date considered is 03/24/2003.

Status of the claims

3. Currently, claims 8-22 and 55-60 are pending in the application. The claims 1-7, 23-54, 61-73 are withdrawn pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Objections

4. The specification is objected to (page 3, line 20-21: "Illustrative polypeptides include polypeptides comprising either amino acid residues SEQ ID NO:3 or amino acid residues SEQ ID NO:3") as being indefinite.

Claims 8, 9, 10,12 and 13 are objected to for depending from the non-elected claim 1.

Claims 56 and 57 are objected to for depending from the claim 55 that contains non-elected subject matter.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-10, 12, 13,15-18, 20, 21, 55-57 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Busfield (US 2002/0164689A1 "Busfield") in view of "Hopp et al." (Hopp, TP and Woods, KR, Proc. Natl. Acad. Sci. USA: **78**, 3824-28, 1981).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

"Busfield" teaches an antibody that selectively binds to an isolated polypeptide consisting of a fragment of a polypeptide comprising the amino acids sequence of SEQ. ID. NO: 2 or 12, wherein the fragment comprises at least 15 contiguous amino acids of SEQ. ID. NO: 2 OR 12 (US 2002/0164689A1 **§** [0169]-(0181]). SEQ. ID. NO: 2 from "Busfield" is identical to SEQ. ID. NO: 2 of the instant application. (see us-10-807-837-2.rapm Result 10) and contains sequence SEQ. ID. NO: 3 from the instant application. "Busfield" teaches that the antibody can be of any type of the following: polyclonal,

murine monoclonal, humanized antibody, human monoclonal or an antibody fragment. Also "Busfield" teaches that the antibody can have any of the following attached to it: a radionuclide, enzyme, substrate, cofactor ,fluorescent marker, chemiluminescent marker, peptide tag, magnetic particle, drug or toxin. Although the sequence PEDPSD is implicitly present in "Busfield", "Busfield" does not teach making an antibody specifically against the PEDPSD hexapeptide. "Hopp et al." teach that the best antigenicity is obtained by using hexapeptides (p.3826-Table 3) and especially peptides rich in P, E and D (p.3826-Table 2). The PEDPSD hexapeptide contains the highest percentage of P, E and D of any contiguous hexapeptide of the SEQ. ID. NO: 2 of the instant application. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make an antibody against a peptide from the polypeptide with the sequence SEQ.ID.NO: 2, based on the teachings of "Busfield". One of ordinary skill in the art at the time of the invention was made have had been motivated to choose the hexapeptide PEDPSD and would have had a reasonable expectation of success because "Hopp et al." teach that hexapeptides rich in P, E and D have the best antigenicity.

Claims 8, 9, 12, 15, 16, 17, 20, 55, 56, 57and 59are rejected under 35 U.S.C. 103(a) as being unpatentable over "Lok et al" (US Patent 5965704.) in view of "Hopp et al." "Lok et al" (column 15, lines 14-24) teaches the use of Zcytor11 (SEQ. ID. NO: 2) polypeptides for preparing antibodies (polyclonal, murine monoclonal, or an antibody fragment) that bind to Zcytor11, which has a sequence identical to sequence SEQ. ID. NO: 2 from the application (the full 574 amino acid sequence). Although the sequence

PEDPSD is implicitly present in the sequence of "Lok et al", "Lok et al" does not teach making an antibody specifically against the hexapeptide. "Hopp et al." teach that the best antigenicity is obtained by using hexapeptides (p.3826-Table 3) and especially peptides rich in P, E and D (p.3826-Table 2). The PEDPSD hexapeptide contains the highest percentage of P, E and D of any contiguous hexapeptide of the SEQ. ID. NO: 2 of the instant application. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make an antibody against a peptide from the polypeptide with the sequence SEQ.ID.NO: 2, based on the teachings of "Busfield". One of ordinary skill in the art at the time of the invention was made have had been motivated to choose the hexapeptide PEDPSD and would have had a reasonable expectation of success because "Hopp et al." teach that hexapeptides rich in P, E and D have the best antigenicity.

Claims 11,14, 19, 22, 58 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of "Busfield" or "Lok et al.", in view of "Hopp et al." and in further view of "Chen et al." (Chen AM, Scott, MD, BioDrugs, 2001; 15(12): 833-47), teach making an antibody against the hexapeptide PEDPSD within SEQ. ID. NO: 2 as set forth supra. None of "Busfield", "Lok et al.", or "Hopp et al." teaches PEGylating the antibody. "Chen et al." teaches that PEGylation of antibodies improves the longevity and vascular retention *in vivo*. In view of the utility of the antibodies claimed in the instant application, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify by PEG the antibodies of either of "Busfield" or "Lok et al." in view of "Hopp et al.", in order to increase the serum half-life, as taught by "Chen et al."

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- obtaining polyclonal antibodies; Green et al., "Production of polyclonal antisera", in Immunochemical protocols (Manson, ed.) pages 1-5 (Humana Press, 1992).
- obtaining murine monoclonal antibodies; Harlow and Lane, "Antibodies-Lab Manual", Cold Spring Harbor Laboratory, 1988, ISBN 0-87969-314-2, Chapter 6, p.148-241.
- obtaining a humanized antibody; Queen et al., U.S. Pat. No. 5,693,762.
- obtaining an antibody fragment; Goldenberg, U.S. Pat. No. 4,331,647.
- obtaining a human monoclonal antibody; Lonberg et al., Nature, **368,** p. 856-9, 1994 or Trakht, I, U.S. Pat. No. 6,197,582.
- obtaining a tagged antibody; Best, U.S. Pat. No. 5,082,928 and von Mehren et al., Ann. Rev. Med., **54**, p.343-69, Epub 2001 Dec 3.
- obtaining a PEGylated antibody; Guernay, U.S. Pat. 6551799.

Conclusion

5. Given the reason stated above all the elected claims (8-22 and 55-60) are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elly-Gerald Stoica whose telephone number is (571) 272-9941. The examiner can normally be reached on 8:30-17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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